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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,948	04/29/2005	David Idris Pritchard	41577/304434	8855

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EXAMINER

HAGOPIAN, CASEY SHEA

ART UNIT	PAPER NUMBER
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1615

MAIL DATE	DELIVERY MODE
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01/05/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/506,948	Applicant(s) PRITCHARD, DAVID IDRIS	
	Examiner Casey S. Hagopian	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 May 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 8-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/6/2004 4/29/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of applicant's Restriction Response filed 5/15/2009.

Election/Restrictions

Claims 8-18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 5/15/2009.

Claim 19 is newly added. Thus, claims 1-7 and 19 are currently under consideration.

Claim Objections

Claim 19 is objected to because of the following informalities: "lacone" is misspelled. Appropriate correction is required.

Claim Rejections - 35 USC § 112, 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 19 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had

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possession of the claimed invention. **This is a new matter rejection.** There is no teaching of “a substance having N-acyl homoserine lactone degradant activity obtained from the secretions/excretions of *Lucilia sericata* or **analogues thereof**” (emphasis added); the subject matter is not properly described as filed. Applicant is invited to identify the portion of the specification that teaches said limitation, as the examiner has not been able to locate the applicable disclosure. The claims within this rejection are examined as written by the applicant; at this time new matter must be considered as part of the claimed subject matter.

Furthermore, M.P.E.P. § 2163 states, “An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention...one must define a compound by 'whatever characteristics sufficiently distinguish it'. A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process.” As such, the specification also does not describe a sufficient number of species as to convey possession of the entire genus encompassed by “a substance having N-acyl homoserine lactone degradant activity obtained from the secretions/excretions of *Lucilia sericata* or **analogs thereof**” (emphasis added).

Claim Rejections - 35 USC § 112, 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 19 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The limitation, "a substance having N-acyl homoserine lactone degradant activity obtained from the secretions/excretions of *Lucilia sericata* or analogues thereof" is indefinite because it is unclear whether "analogues thereof" is referring to "a substance having N-acyl homoserine lactone degradant activity" or "secretions/excretions of *Lucilia sericata*". Correction/clarification is respectfully requested.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-5 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over European Patent (EP 1020197) as evidenced by Fleischmann (USPN 6,359,189 B1) and in view of Hinshaw J. "Larval Therapy: A Review of Clinical Human and Veterinary Studies".

Fleishmann teaches a bandage for treatment of wounds comprising a wound overlay (i.e., a medical device) comprising secretion of fly larvae (abstract). Fleishmann teaches the particular fly larvae, *Lucilia sericata* (col. 1, lines 13) and discusses their effectiveness against bacterial infections (col. 1, lines 17-18 and 52-53). Additionally, the wound overlay comprises plastic (col. 3, lines 20-23). It is noted that the secretions/excretions of *Lucilia sericata* necessarily have N-acyl homoserine lactone degradant activity. Thus, the composition taught by Fleishmann would also necessarily have N-acyl homoserine lactone degradant activity.

Fleishmann is silent to the particular bacteria being *Pseudomonas aeruginosa* or *Staphylococcus aureus*.

Hinshaw teaches the effectiveness of the secretions of *Lucilia sericata* against infections containing bacteria such as methicillin-resistant *Staphylococcus aureus* (MRSA) and *Pseudomonas aeruginosa* (pages 2-3).

One of ordinary skill in the art would have been motivated to apply the composition taught by Fleishmann to a wound containing the particular bacteria, *Staphylococcus aureus* and *Pseudomonas aeruginosa* for the purpose of wound healing. A practitioner would reasonably expect applying a wound dressing containing secretions/excretions of *Lucilia sericata* to effectively treat a wound containing

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Staphylococcus aureus or *Pseudomonas aeruginosa*. Thus, in Fleishmann, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include treating a surface populated with the particular bacteria, *Pseudomonas aeruginosa* or *Staphylococcus aureus* as suggested by Hinshaw.

Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over European Patent (EP 1020197) as evidenced by Fleischmann (USPN 6,359,189 B1) and in view of Hinshaw J. "Larval Therapy: A Review of Clinical Human and Veterinary Studies" and further in view of Shimamura et al. (USPN 5,807,564).

Fleishmann and Hinshaw teach the elements discussed above.

Fleishmann and Hinshaw are silent to additionally including an antibiotic, in particular tetracycline.

Shimamura et al. teaches an antibiotic composition effective against methicillin resistant *Staphylococcus aureus* comprising tetracycline (claim 1).

It has been held that combinations of two or more compositions each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is to be used for the very same purpose. In re Susi, 58 CCPA 1074, 1079-80, 440 F.2d 442, 445, 169 USPQ 423, 426 (1971).

Also, it is generally considered to be *prime facie* obvious to combine compounds each of which is taught by the prior art to be useful for the same purpose in order to form a composition that is to be used for an identical purpose. The motivation for combining them flows from their having been used individually in the prior art, and from

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them being recognized in the prior art as useful for the same purpose. As shown by the recited teachings, instant claims are no more than the combination of conventional components of secretions/excretions of *Lucilia sericata* and a composition comprising tetracycline for the purpose of treating bacterial infections such as those caused by *Staphylococcus aureus*. It therefore follows that the instant claims define *prime facie* obvious subject matter. Cf. *In re Kerhoven*, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980).

Conclusion

All claims have been rejected; no claims are allowed.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Casey Hagopian whose telephone number is 571-272-6097. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax, can be reached at 571-272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Casey S Hagopian/
Examiner, Art Unit 1615

/Robert A. Wax/
Supervisory Patent Examiner, Art Unit 1615